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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,848	04/22/2002	Zdenek Kratky	112843-034	1858

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/02/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

10/019,848

Applicant(s)

KRATKY ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____.

Detailed Action

The Preliminary Amendment filed April 22, 2002 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1-20 have been amended.

New claims 21-39 have been entered.

An action on the merits of claims 1-39 is contained herein below.

Specification

The disclosure is objected to because of the following informalities: page 3, lines 9-19 discuss the amounts of protein which are preferably used in the composition. Applicants state that the composition comprises about 6% to about 50% whey protein, more preferably 20%-40%, and most preferably 30%. Applicants then state that the composition comprises from about 20% to 40% casein protein, and preferably about 30%. Applicants then say the ratio of whey protein to casein protein is about 60:40 to about 70:30, most preferably 70:30. It is unclear if this is an error as the most preferred percentage of each protein is 30%, which would thus give a range of 1:1, not 7:3 (70:30).

Appropriate correction is required.

Claim Objections

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim provides the limitation of the composition comprising casein protein, but claim 18, the claim from which claim 23 depends from, is drawn to a method of producing an infant formula by blending whey protein and casein protein together.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite wherein the claim recites "a composition for an infant formula comprising a protein source which has a low threonine content and comprising...". It is unclear what is intended by "a protein source". A protein source could be meat, milk, or eggs. The claim is interpreted as "a composition comprising protein which has a low threonine content...".

Additionally, it is unclear if the following components, the whey, free arginine, free histidine, etc. in the claim are intended as additional agents incorporated in the composition or if these

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components are defining the protein which has a low threonine content. All claims which contain these recitations without clearly stating that which applicant intends are also indefinite.

The term “**low threonine content**” in claim 1 for example, is a relative term which renders the claim indefinite. The term “low” is not defined by the claim, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The term “low” is indefinite in all claims in which it occurs without defining what is intended by “low”.

The term “**tryptophan rich milk protein**” in claim 1 for example, is a relative term which renders the claim indefinite. The term “tryptophan rich” is not defined by the claim, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The term “tryptophan rich” is indefinite in all claims in which it occurs without defining what is intended by said term.

Claim 3 is indefinite wherein it is unclear as to what is intended by “a composition comprises about 9.0 to about 10.0 w/w% of protein”. The examiner is interpreting this as “a composition comprising about 9 to 10% protein based on the weight of the composition”. OK

^{check this w/ all parties}
The term “**substantially free**” in claim 6 for example, is a relative term which renders the claim indefinite. The term “substantially free” is not defined by the claim, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The term “substantially free” is indefinite in all claims in which it occurs without defining what is intended by said term.

Claim 10 is indefinite wherein the claim provides limitations on the amino acids, i.e. “about 0.1% to about 3% by weight of arginine”. Claim 19 depends from claim 1, and claim 1 has the limitation of a composition comprising “free arginine”. It is unclear if applicant intends

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the composition to comprise arginine and free arginine, or if the free arginine of claim 1 is being limited to said percentages. Likewise, the claim is drawn to percentages of tryptophan and tyrosine wherein the previous claim is drawn to the free amino acids. The terminology should be consistent with all claims or clarity should be made to allow for understanding that these amino acids are added in the composition in addition to the free versions.

Claim 11 is indefinite wherein the claim provides limitations wherein the composition of claim 1 "comprises a lipid source and a carbohydrate source". It is unclear if applicant intends to add compounds which are sources for making lipids and carbohydrates, or if they intend to add lipids and carbohydrates.

The term "includes" is indefinite, in claim 12 for example. It is unclear as to what applicant intends by the use of "includes". The standard terminology in current patent practice entails using "comprising", "consisting of", or "consisting essentially of" which provide definite guidance as to whether the phrase is an open phrase, or if it is closed. The term is indefinite in all instances in the claims wherein the claim does not provide definite guidance as to the scope of what is intended.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

It is noted that due to the confusing nature of the claims, the examiner has been unable to determine exactly that which applicant intends as their invention in regards to the composition. The uncertainty stems from whether applicants intend the broad composition to comprise: (1) a

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protein with a low threonine content; a whey component (acid or sweet with macropeptide removed); free arginine; free histidine; and any of free tyrosine, free tryptophan, tryptophan rich milk, or a mixture thereof; or (2) a protein with a low threonine content which comprises: a whey component (acid or sweet with macropeptide removed); free arginine; free histidine; and any of free tyrosine, free tryptophan, tryptophan rich milk, or a mixture thereof. The examiner will make a further determination of patentability of the compositions as claimed upon clarity of the subject matter at hand.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harzer et al. (EPO 418 593 A2).

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Claim 18 is drawn to a method of producing an infant formula comprising blending whey protein and casein protein with free arginine, free histidine, and any of free tyrosine, free tryptophan, or tryptophan rich milk protein, and then homogenizing the blended mixture.

Harzer et al. disclose a method of making an infant formula comprising the steps of stirring with an intensive stirrer protein concentrates and L-amino acids until the mixture is homogenous and then carrying out homogenization (page 7, 2nd and 3rd paragraphs). Harzer et al. then disclose that the intact proteins can be replaced with hydrolyzed proteins, such as whey hydrolysates, casein hydrolysates, etc. (page 8, 2nd paragraph). The amino acids disclosed to be added to the compositions include histidine, isoleucine, leucine, valine, and tyrosine to name a few (see the compositions in examples). Additionally, they are taught to be added in their free form (page 3, 4th full paragraph). What is not taught is to specifically add free arginine.

When determining the patentability of process of making claims, the determination is based on the inventiveness of the process steps themselves, and not necessarily on the compositions/compounds of the process (SEE *Ex parte Ochiai (BPAI 1992) 24 PQ2d 1265*). In the instant case, the process of blending the mixture with subsequent homogenization is known in the art. One of ordinary skill in the art would recognize that adding another or a different amino acid would not effect the known process to obtain an improved process, but merely provide an end product which has slightly different properties which is based solely on the "ingredients" of the process, not based on the methodological steps. The instant method is not seen as an improvement over the prior art, as all methodological steps are correlative to those of the prior art.

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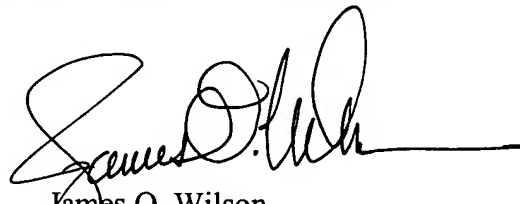
It is noted that the closest prior art the examiner would like to make of record is Harzer et al. (EPO 418 593 A2), Martinez et al. (US Patent 5,405,637) and Gaull et al. (US Patent 4,303,692).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623

Traviss C. McIntosh
May 30, 2003